General

Guideline Title

Evaluation and management of gallstone-related diseases in non-pregnant adults.

Bibliographic Source(s)

University of Michigan Health System. Evaluation and management of gallstone-related diseases in non-pregnant adults. Ann Arbor (MI): University of Michigan Health System; 2014 May. 14 p. [24 references]

Guideline Status

This is the current release of the guideline.

The University of Michigan Health System released a minor revision in October 2014 to include updated information regarding ultrasound findings suggestive of acute cholecystitis.

Recommendations

Major Recommendations

Note from the University of Michigan Health System (UMHS) and the National Guideline Clearinghouse (NGC): The following guidance was current as of May 2014. Because UMHS occasionally releases minor revisions to its guidance based on new information, users may wish to consult the original guideline document for the most current version.

Note from NGC: The following key points summarize the content of the guideline. Refer to the full text of the original guideline document for detailed information on each of the screening procedures.

The strength of recommendation (I-III) and levels of evidence (A-D) are defined at the end of the "Major Recommendations" field.

Key Points

Clinical Presentation

Patients presenting with upper abdominal pain or jaundice should be evaluated for gallstone-related disease.

Diagnosis

The evaluation for gallstone-related disease is summarized in Table 1 of the original guideline document. The evaluation routinely includes:

1. Complete physical exam

2. Laboratory evaluation – complete blood count (CBC), comprehensive metabolic panel, amylase/lipase
3. Imaging – right upper quadrant (RUQ) ultrasound

In the vast majority of patients with acute cholecystitis, the diagnosis can be made based upon the history, physical findings, laboratory tests, and ultrasound (see Table 3 in the original guideline document for ultrasound findings that are suggestive of acute cholecystitis). In rare cases where the diagnosis of cholecystitis remains uncertain after this evaluation, additional imaging modalities may be necessary.

Treatment

The treatment of gallstone-related diseases is summarized in Figure 1 in the original guideline document.

Biliary Colic

1. Minimally symptomatic or with symptoms that resolve: Provide reassurance, education on avoidance of triggers (e.g., dietary fat). Provide direct referral to elective surgery (at University of Michigan, Priority Gallbladder Clinic for surgery within 2 weeks, see Appendix A in the original guideline document) *[II-C]*.
2. Moderate to severe symptoms: Consult surgery. Perform non-urgent laparoscopic cholecystectomy during same visit *[II-C]*. Timing of surgery determined by patient preference and operating room availability.

Acute Cholecystitis

1. Admit to Surgery.
2. Initiate intravenous (IV) antibiotics (see Table 2 in the original guideline document). Perform laparoscopic cholecystectomy within 24 to 48 hours *[I-A]*.
    - In patients without gallstones who have RUQ and/or epigastric pain and a hepatobiliary iminodiacetic acid (HIDA) scan showing delayed gallbladder filling or lack of gallbladder emptying, cholecystectomy should be recommended *[I-A]*.

Choledocholithiasis

1. Evaluate for evidence of cholangitis. If suspected, treat as cholangitis (below).
2. If no evidence of cholangitis, admit to surgery and prepare for cholecystectomy.
3. Estimate the likelihood of choledocholithiasis (see Table 4 in the original guideline document).
    a. For low likelihood, no additional evaluation is needed, and routine intraoperative cholangiography (IOC) is not recommended *[III-B]*.
    b. For intermediate risk, recommended approach is a one-stage procedure with laparoscopic cholecystectomy with IOC within 48 hours of admission (preferably within 24 hours) *[I-A]*. Alternate approaches might include preoperative imaging with endoscopic ultrasound (EUS) or magnetic resonance cholangiopancreatography (MRCP), especially if IOC will not be performed.
        i. If IOC demonstrates a retained common bile duct (CBD) stone:
            1. Perform procedure to remove CBD stones during the same operation *[I-A]*, or
            2. Obtain gastroenterology consult within 24 hours after surgery for endoscopic retrograde cholangiopancreatography (ERCP).
    c. For high risk patients, or those with documented choledocholithiasis, preoperative ERCP is often performed to clear the duct.

Cholangitis

1. Admit to Medicine service.
2. Initiate IV antibiotics, nil per os (nothing by mouth, NPO) (see Table 2 in the original guideline document).
3. Obtain Gastroenterology consult.
4. Classify severity of acute cholangitis (see Table 6 in the original guideline document).
    a. If mild cholangitis with adequate response to medical therapy: ERCP within 72 hours.
    b. If moderate-severe and not responsive to medical therapy: ERCP within 24 hours.
5. Consult surgery for laparoscopic cholecystectomy during same admission, after cholangitis resolves.

Gallstone Pancreatitis

1. Evaluate for evidence of cholangitis. If suspected, treat as cholangitis (above).
2. Classify severity of gallstone pancreatitis (see Table 7 in the original guideline document).
   Mild Gallstone Pancreatitis

a. Admit to Surgery service.
b. Perform laparoscopic cholecystectomy with IOC within 48 hours (preferably 24 hours) *[I-B]*.
c. If IOC demonstrates a retained CBD stone:
    1. Surgical removal of CBD gallstone *[I-A]*, or
    2. Gastroenterology consult for ERCP within 24 hours of surgery.

Moderate to Severe Gallstone Pancreatitis

a. Admit to Medicine.
b. Consider Gastroenterology consultation.
c. Delay cholecystectomy until pancreatitis resolves.

3. For detailed management of acute pancreatitis, see other resources.

Definitions:

Levels of Evidence

A. Randomized controlled trials
B. Controlled trials, no randomization
C. Observational trials
D. Opinion of expert panel

Strength of Recommendation

I. Generally should be performed
II. May be reasonable to perform
III. Generally should not be performed

Clinical Algorithm(s)

An algorithm titled "Treatments for Gallstone-Related Diseases" is provided in the original guideline document.

Scope

Disease/Condition(s)

Gallstone-related diseases, including biliary colic, acute cholecystitis, choledocholithiasis, cholangitis, and gallstone pancreatitis

Guideline Category

Diagnosis

Evaluation

Management

Treatment

Clinical Specialty

Emergency Medicine

Gastroenterology

Internal Medicine

Radiology

Surgery

Intended Users

Advanced Practice Nurses

Emergency Medical Technicians/Paramedics

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To create an evidence-based standard for the management of gallstone-related diseases that provides prompt and appropriate service to patients, reduces unnecessary diagnostic tests, and improves patient outcomes

Target Population

Adult patients with suspected or confirmed biliary colic, acute cholecystitis, choledocholithiasis, cholangitis, or mild gallstone pancreatitis

Note: Pregnant patients and patients with a history of gastric bypass surgery or biliary surgery are excluded from this guideline. This document does not provide detailed recommendations for the general care of patients with acute pancreatitis.

Interventions and Practices Considered

Diagnosis/Evaluation/Risk Assessment

1. Assessment of history and symptoms
2. Complete physical exam
3. Laboratory evaluation: complete blood count (CBC), comprehensive metabolic panel, amylase/lipase
4. Right upper quadrant (RUQ) ultrasound
5. Cholescintigraphy scan (hepatobiliary iminodiacetic acid [HIDA] scan)
6. Risk stratification for the probability of choledocholithiasis
7. Severity classification for acute cholangitis
8. Classification of gallstone pancreatitis: Ranson and BISAP criteria

Treatment/Management

1. Reassurance and education on avoidance of triggers
2. Preoperative antibiotic therapy
3. Laparoscopic cholecystectomy
4. Gastroenterology and surgery consultation
5. Endoscopic retrograde cholangiopancreatography (ERCP)
6. Laparoscopic cholecystectomy with intraoperative cholangiography (IOC)

Major Outcomes Considered

- Sensitivity and specificity of diagnostic tests
- Ductal clearance rates

- Risk of recurrent biliary events
- Morbidity
- Mortality

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

The literature search for this guideline was conducted in Medline prospectively using major key words: biliary colic, cholecystitis, cholangitis, choledocholithiasis, gallstone pancreatitis. The search was limited to human adults population, and published in the English language between January 2009 and June 2013.

Additional key words included: clinical protocols, physician practice patterns, algorithms, consensus development conferences, practice guidelines, guidelines, outcomes and process assessment (health care); clinical trials, controlled clinical trials, multicenter studies, randomized controlled trials, cohort studies, meta-analysis or meta-analyses; diagnosis, diagnostic use, sensitivity and specificity, false negative reactions, false positive reactions, likelihood functions, sensitivity, specificity; predictive value therapy, drug therapy, antibiotics, ultrasound, HIDA, CT, MRCP, cholangiopancreatography, endoscopic ultrasound, cholecystography, cholangiography, cholecystectomy, percutaneous cholecystostomy tube (PCT), biliary drainage tube, endoscopic retrograde, IOC.

The search was conducted in components each keyed to a specific causal link in a formal problem structure (available upon request). The search was supplemented with very recent clinical trials known to expert members of the panel. The search was a single cycle.

Within the Cochrane Database of Systematic Reviews, 18 reviews were found using the strategy in the search strategies document.

The literature search revealed 10 established national guidelines specifically addressing gallstone-related diseases.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Levels of Evidence

A. Randomized controlled trials
B. Controlled trials, no randomization
C. Observational trials
D. Opinion of expert panel

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

Not stated

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Conclusions were based on prospective randomized clinical trials if available, to the exclusion of other data; if randomized controlled trials were not available, observational studies were admitted to consideration. If no such data were available for a given link in the problem formulation, expert opinion was used to estimate effect size.

Rating Scheme for the Strength of the Recommendations

Strength of Recommendation

I. Generally should be performed
II. May be reasonable to perform
III. Generally should not be performed

Cost Analysis

A formal cost analysis was not performed and published analyses were not reviewed.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

Drafts of this guideline were reviewed in clinical conferences and by distribution for comment within departments and divisions of the University of Michigan Health System to which the content is most relevant: Emergency Medicine, Family Medicine, General Medicine, Infectious Disease, Gastroenterology, and Radiology. Medication recommendations were reviewed by the Pharmacy and Therapeutics Committee. The final version was endorsed by the Clinical Practice Committee of the University of Michigan Faculty Group Practice and the Executive Committee for Clinical Affairs of the University of Michigan Hospitals and Health Centers.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for select recommendations (see the "Major Recommendations" field).

Conclusions were based on prospective randomized clinical trials (RCTs) if available, to the exclusion of other data; if RCTs were not available, observational studies were admitted to consideration. If no such data were available for a given link in the problem formulation, expert opinion was used to estimate effect size.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Accurate diagnosis and appropriate management of adults with gallstone-related diseases

Potential Harms

- Routine intraoperative cholangiography (IOC) may be associated with increased operative times and increased perioperative complication rates.
- The risks of endoscopic retrograde cholangiopancreatography (ERCP) include post-procedure pancreatitis (risk factors include young age and female gender).

Qualifying Statements

Qualifying Statements

- These guidelines should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific clinical procedure or treatment must be made by the physician in light of the circumstances presented by the patient.
- This guideline is not comprehensive, but can guide the care of the majority of patients with gallstone-related disease.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Clinical Algorithm

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

IOM Domain

Effectiveness

Timeliness

Identifying Information and Availability

Bibliographic Source(s)

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Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2014 May

Guideline Developer(s)

University of Michigan Health System - Academic Institution

Source(s) of Funding

University of Michigan Health System

Guideline Committee

Gallstone-Related Diseases Guideline Team

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Financial Disclosures/Conflicts of Interest

The University of Michigan Health System endorses the Guidelines of the Association of American Medical Colleges and the Standards of the Accreditation Council for Continuing Medical Education that the individuals who present educational activities disclose significant relationships with commercial companies whose products or services are discussed. Disclosure of a relationship is not intended to suggest bias in the information presented, but is made to provide readers with information that might be of potential importance to their evaluation of the information.

No team members reported conflicts of interest.

Guideline Status

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Guideline Availability

Electronic copies: Available from the University of Michigan Health System Web site .

Availability of Companion Documents

None available

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on June 29, 2014.

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